ORIGINAL

IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO
CIVIL DIVISION

MICHELLE & CHARLIE BEAVAN
875 Autumn Ct.
Trenton, OH 45067

Plaintiff,

v.

ABUBAKAR ATIQ DURRANI, M.D.,
Pakistan
(Served via Hague Convention)

And

CENTER FOR ADVANCED SPINE TECHNOLOGIES, INC.
(Served via Hague Convention)

And

JOURNEY LITE OF CINCINNATI, LLC
10475 READING RD., SUITE 115
CINCINNATI, OH 45241

SERVE: CT CORPORATION SYSTEM
1300 EAST NINTH STREET
CLEVELAND, OH 44114
(Serve via Certified mail)

REGULAR MAIL WAIVER

And

BARIATRIC PARTNERS OF TEXAS, INC.
Serve:
CT CORPORATION
150 FAYETTEVILLE STREET
BOX 1011
RALEIGH, NC 27601

REGULAR MAIL WAIVER

(Serve via Certified mail)

Case No. A 1 5 0 5 4 2 3

JUDGE

COMPLAINT
& JURY DEMAND

(ALL NEW DR. DURRANI CASES SHALL GO TO JUDGE RUEHLMAN PER HIS ORDER)

FILED
2015 OCT -9 P 12:49
CLERK OF COURTS
HAMILTON COUNTY, OH

EXHIBIT A

D112238054 INI

And

BARIATRIC PARTNERS OF TEXAS, LLC

Serve:
MYA RA, LLC
150 FAYETTEVILLE STREET
BOX 1011
RALEIGH, NC 27601

REGULAR MAIL WAIVER

And

ASCIRA PARTNERS, LLC

Serve:
JOHN W. TITUS
1600 DIVISION STREET
SUITE 700
NASHVILLE, TN 37203-2271

REGULAR MAIL WAIVER

And

TRACE CURRY
Journey Lite of Cincinnati LLC
CT Corporation Systems
1300 East 9th Street
Cleveland OH 44114

REGULAR MAIL WAIVER

And

ELLIOTT FEGELMAN
10475 READING ROAD
CINCINNATI, OH 45241

REGULAR MAIL WAIVER

And

JEFFREY A. BOGLE
4009 HILLSBORO PIKE
SUITE 209
NASHVILLE, TN 37215

REGULAR MAIL WAIVER

And

MICHAEL GOULD
4009 HILLSBORO PIKE
SUITE 209

REGULAR MAIL WAIVER

NASHVILLE, TN 37215

And

DAVID E. MCCLELLAN
10475 READING ROAD
SUITE 115
CINCINNATI OH, 45220

REGULAR MAIL WAIVER

Defendants.

Come now Plaintiffs, Michelle and Charlie Beavan, and file this Complaint and jury demand and state as follows:

1. At all times relevant, Plaintiffs were residents of and domiciled in the State of Ohio.
2. At all times relevant, Defendant Dr. Abubakar Atiq Durrani (hereinafter "Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.
3. At all times relevant, Center for Advanced Spine Technologies, Inc. (hereinafter "CAST"), was licensed to and did in fact perform medical services in the State of Ohio, and was and is a corporation authorized to transact business in the State of Ohio and Kentucky.
4. At all times relevant, Journey Lite of Cincinnati, LLC ("Journey Lite") was a Delaware corporation transacting business and performing and managing medical services in the State of Ohio and held itself out to the public, and specifically to the Plaintiff as a center providing competent and qualified medical and nursing services, care and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.
5. Defendants, Bariatric Partners of Texas Inc., Bariatric of Texas, LLC, Ascira

Partners, LLC, and Center for Advanced Spine Technologies, Inc. and/or were also owners and/ or managers of Journey Lite.

6. David McClellan is the Controller/Administrator of Journey of Cincinnati, LLC and involved with the management of Journey Lite.
7. Dr. Durrani, Trace Curry, Elliott Fegelman and Bariatric Partners, Inc were owners and directors of CAST.
8. The amount in controversy exceeds the jurisdictional threshold of this Court.
9. The subject matter of the Complaint arises out of medical treatment by the Defendants in Hamilton County, Ohio. This Court is thus the proper venue to grant the Plaintiff the relief she seeks.
10. The amount in controversy exceeds the jurisdictional threshold of this Court.
11. The subject matter of the Complaint arises out of medical treatment by Defendants in Hamilton County, Ohio. This Court is thus the proper venue to grant Plaintiff the relief sought.
12. This case was previously set for trial and Plaintiff's 41(A) Voluntarily Dismissed this case and are now re-filing this case.

FACTUAL ALLEGATIONS OF PLAINTIFF

13. In January 2013, Plaintiff's primary care physician, Dr. Schumulewitz, referred her to Dr. Durrani at his CAST office.
14. At the time, Plaintiff was experiencing pain in her neck, as well as numbness and tingling sensations radiating down into her left arm.

15. Dr. Durrani ordered Plaintiff to have x-rays taken prior to their first consultation. Upon review of the x-ray films, Dr. Durrani immediately recommended that Plaintiff undergo surgery.
16. Dr. Durrani assured the Plaintiff that he could "fix" her.
17. On March 29, 2013, Dr. Durrani performed surgery on the Plaintiff consisting of an anterior cervical fusion with the installation of hardware at Journey Lite.
18. Plaintiff was discharged the same day, and attended follow-up appointments with Dr. Durrani for steroid injections and regular check-ups.
19. During her two-week follow-up with Dr. Durrani, he told Plaintiff that she could discontinue using the hard neck brace she had been wearing since the surgery and transition to a soft neck brace.
20. Shortly after moving to the soft neck brace, Plaintiff began to suffer from sharp pains in both sides of her neck radiating down her spine. In addition, the tingling sensations she had previously suffered from returned much worse than before, now extending all the way down her arms to her fingertips.
21. Plaintiff also lost much of her flexibility, and must now regularly wear a neck brace to stabilize her head.
22. Though Plaintiff has thought to seek the advice of other healthcare professionals to correct the damage done to her cervical spine, she is too afraid of the possible harm that could come to her as a result of Dr. Durrani's surgery.
23. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off–label" and/or Puregen without Ms. Shepherd's knowledge or consent, causing Ms. Shepherd harm.

24. The use of BMP-2 increases a person's chance of cancer by 3.5%.

25. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

26. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result Plaintiff has an increased fear of cancer.

27. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

28. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

29. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' records.

MORE SPECIFIC ALLEGATIONS BASED UPON DISCOVERY AND DEPOSITION TESTIMONY

30. This information is to demonstrate the overall negligence and inappropriate actions of Dr. Durrani and the hospitals he worked with and/or for and/or in an individual capacity.

31. Krissy Probst was Dr. Durrani's professional and personal assistant handling professional, academic, travel, surgery scheduling, his journals, his Boards, his credentialing, his personal affairs and his bills.

32. Krissy Probst worked as Dr. Durrani's assistant for three years at Children's Hospital from 2006, 2007, and 2008.

33. Krissy Probst reported Dr. Durrani to Sandy Singleton, the Business Director at Children's for his having an affair with Jamie Moor, his physician assistant.

34. Krissy Probst resigned in 2008 from Dr. Durrani and remained working for three other surgeons in the Orthopedic Department.

35. Krissy Probst worked in the Orthopedic Department for eleven years from 2002-2013. She retired in May, 2013.

36. Krissy Probst confirmed Dr. Durrani claims being a Prince, when he is not.

37. According to Krissy Probst, Dr. Crawford, an icon in pediatric orthopedics treated Dr. Durrani "like a son."

38. According to Krissy Probst, Dr. Crawford, Chief of Orthopedics at Children's unconditionally supported Dr. Durrani no matter the issues and problems Dr. Durrani faced.

39. Dr. Durrani's patient care at Children's Hospital dropped off considerably after Jamie Moor became his physician assistant and they began their affair.

40. Dr. Durrani was the only orthopedic spine surgeon at Children's who would perform a dangerous high volume of surgeries.

41. At Children's, Dr. Durrani would begin a surgery, leave and have fellows and residents complete a surgery or do the full surgery while he was in his office with Jamie Moor, his physician assistant for four or five hours.

42. Children's Board and administration knew about Dr. Durrani doing too many surgeries and not properly doing the surgeries. They did nothing.

43. Dr. Durrani argued to Children's administration when they complained to him that he made them money so Children's tolerated him and allowed him to do what he wanted.

44. Dr. Durrani, when told by Children's that Jamie Moor had to leave, told Children's that he would leave too.

45. Dr. Agabagi would do one spine patient a day at Children's because it takes normally eight hours for a full fusion.

46. Dr. Durrani would schedule two to three spine surgeries a day at Children's.

47. Dr. Durrani would repeatedly have the Business Director, Sandy Singleton, or OR Director allow him to add surgeries claiming they were emergencies when they were not.

48. Dr. Durrani would leave a spine surgery patient for four or five hours in the surgery suite under the care of fellows or residents, unsupervised and sit in his office and check on the surgery as he pleased.

49. Dr. Peter Stern did not like Dr. Durrani while Dr. Durrani was at Children's because he knew all about his patient safety risk issues. Yet, Dr. Stern supported, aided and abetted Dr. Durrani's arrival at West Chester. It defies comprehension, but was for one of the world's oldest motives—greed of money.

50. There is also a Dr. Peter Sturm, an orthopedic at Children's who also had no use for Dr. Durrani.

51. Dr. Durrani chose his own codes for Children's billing which he manipulated with the full knowledge of Children's Board and management.

52. Dr. Durrani was dating and living with Beth Garrett, a nursing school drop-out, with the full knowledge of his wife Shazia.

53. Dr. Durrani was close with David Rattigan until David Rattigan pursued Jamie Moor and Dr. Durrani would not allow David Rattigan in the OR at Children's for a long time.

54. Dr. Durrani, while claiming to have riches, does not. Dr. Durrani's wife's family paid for Dr. Durrani's education and it is her family with the significant wealth.

55. Medtronics paid for Dr. Durrani's trips and paid him $10,000 fees for speaking or simply showing up at a spine conference.

56. Krissy Probst's business director told her to save all Dr. Durrani related documents and information and she did.

57. While doing research at Children's, Dr. Durrani would misstate facts regarding his research. Children's knew he did this.

58. Dr. Durrani ended on such bad terms with Children's Hospital he was not allowed on the premises after his departure in December 2008, yet he performed a spine surgery there in February 2009.

59. Eric J. Wall, MD was the Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

60. Sandy Singleton, MBA was the Senior Business Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.

61. On information and belief, Dr. Durrani used his relationships with Children's officials to purge his Children's file of all patient safety and legal issues which had occurred as part of his departure "deal" which Defendants hide with privilege.

INFUSE/BMP-2

I. BACKGROUND INFORMATION

62. The Deters Law Firm, P.S.C., represents approximately 500 Plaintiffs in medical malpractice actions against a former Northern Kentucky/Cincinnati-area spine surgeon named Abubakar Atiq Dr. Durrani (Dr. Durrani), his company, Center for Advanced Spine Technologies, Inc. (CAST), and several area hospitals including, but not limited to, West Chester Hospital (WCH), University of Cincinnati Health (UC Health), Cincinnati Children's Hospital Medical Center (CCHMC), Christ Hospital, Deaconess Hospital, Good Samaritan Hospital and Journey Lite of Cincinnati, LLC (Journey Lite) (collectively Hospitals).

63. Dr. Durrani performed unnecessary, fraudulent, dangerous, and ultimately damaging surgeries on these Plaintiffs while working for and with these Hospitals.

64. The scheme and artifice to defraud that Dr. Durrani devised, executed, and attempted to execute while working for and with the Hospitals included the following patterns and practices:

    a. Dr. Durrani persuaded the patient that surgery was the only option, when in fact the patient did not need surgery.

    b. Dr. Durrani told the patient that the medical situation was urgent and required immediate surgery. He also falsely told the patient that he/she was at risk of grave injuries without the surgery.

    c. Dr. Durrani often told his cervical spine patients that they risked paralysis or that his/her head would fall off if he/she was involved in a car accident,

ostensibly because there was almost nothing attaching the head to the patient's body.

d. Dr. Durrani often ordered imaging studies such as x-rays, CT scans, or MRIs for patients but either did not read or ignored the resulting radiology reports.

e. Dr. Durrani often provided his own exaggerated and dire reading of the patient's imaging study that was either inconsistent with or was plainly contradicted by the radiologist's report. At times, Dr. Durrani provided a false reading of the imaging.

f. Dr. Durrani often dictated that he had performed certain physical examinations and procedures on patients that he did not actually perform.

g. Dr. Durrani often ordered a pain injection for a level of the spine that was inconsistent with the pain stated by the patient or with that indicated by the imaging. Dr. Durrani also scheduled patients for surgeries without learning of or waiting for the results of certain pain injections or related therapies.

h. Dr. Durrani often dictated his operative reports or other patient records months after the actual treatment had occurred.

i. Dr. Durrani's operative reports and treatment records contained false statements about the patient's diagnosis, the procedure performed, and the instrumentation used in the procedure.

j. When a patient experienced complications resulting from the surgery, Dr. Durrani at times failed to inform the patient of, or misrepresented the nature of, the complications.

k. All of the above-mentioned actions were done with the knowledge, cooperation, or intentional ignorance of the Hospitals because Dr. Durrani was one of the biggest moneymakers for the Hospitals.

65. In addition to the civil medical malpractice actions against Dr. Durrani, on August 7, 2013, he was indicted by the Federal Government for performing unnecessary surgeries and for defrauding the Medicare and Medicaid programs. Specifically, the ten-count complaint charged Dr. Durrani with health care fraud, in violation of 18 U.S.C. § 1347, and making false statements in health care matters, in violation of 18 U.S.C. § 1035. There was a subsequent superseding indictment adding over 30 counts.

66. Following these criminal indictments, in December of 2013 and prior to the first Plaintiff's trial in these actions, Dr. Durrani fled the United States and returned to Pakistan. He has not returned to the United States to face allegations of either criminal or civil liability.

67. Among Dr. Durrani's and the Hospitals' professional failings was the use of a synthetic bone-morphogenetic protein called BMP-2, which was marketed under the trade name "Infuse." Dr. Durrani used BMP-2/Infuse in ways that were either not approved by the federal Food and Drug Administration (FDA) or that were specifically contraindicated as noted on the FDA-approved product labeling. The Defendants had full knowledge of this fact.

68. BMP-2/Infuse was, at the time of the surgeries in question, and currently still is manufactured by a company called Medtronic, Inc. (Medtronic).

69. Dr. Durrani predominantly used BMP-2/Infuse on patients at WCH, which is owned by UC Health.

70. It is Plaintiffs' position that this non-FDA-approved use of BMP-2/Infuse was not only negligent, and fraudulent, but criminal based upon the manner in which it was allowed to be used by Dr. Durrani at West Chester, all with the knowledge and full support of the Defendants.

II. THE PLAYERS REGARDING BMP-2

71. Dr. Durrani is a citizen of the Republic of Pakistan and was a permanent resident of the United States who, from approximately 2005 to 2013, worked as a spine surgeon in and around Cincinnati, Ohio, until he fled the United States to escape civil liability and criminal prosecution.

72. Medtronic is an Irish corporation, with its principal executive office located in Dublin, Ireland, and its operational headquarters located in Minneapolis, Minnesota. Medtronic is the world's third largest medical device company and manufactures and markets BMP-2/Infuse. Medtronic sales representatives were also present during the experimental surgeries performed on Plaintiffs, who are clients of the Deters Law Firm.

73. CAST was a corporation organized under the laws of Ohio and had business and medical offices in Florence, Kentucky and Evendale, Ohio. CAST was owned, in whole or in part, by Dr. Durrani.

74. Bahler Medical, Inc. is a manufacturer of medical implants and is a corporation located in the state of Ohio.

75. David Rattigan is an Ohio resident and was and is a sales representative for Medtronic. Further, he is affiliated with Bahler Medical, Inc., was involved in many of the transactions involving BMP-2, and was present for the experimental surgeries in which BMP-2 was used.

76. West Chester Hospital, LLC is a corporation organized under the laws of Ohio. It provides medical facilities and billing support to physicians, including Dr. Durrani, in the state of Ohio. WCH is owned by UC Health.

77. UC Health is a private, non-profit corporation organized under the laws of Ohio. It provides medical facilities, management, administrative, ancillary, and billing support to physicians, and it owns WCH.

78. CCHMC is a medical facility in Ohio where Dr. Durrani was an employee until approximately 2008.

III. WHAT IS BMP-2/INFUSE?

79. The full name of BMP-2 is "Recombinant Human Morphogenetic Protein-2" (also called rhBMP-2). The following definitions apply:

    a. Recombinant – Artificially created in a lab;

    b. Morphogenetic – Evolutionary development of an organism;

    c. Protein – Essential for growth and repair of tissue.

80. Recombinant human protein (rhBMP-2) is currently available for orthopedic usage in the United States.

81. Medtronic manufactured, marketed, sold, and distributed BMP-2 under the trade name "Infuse."

82. BMP-2 has been shown to stimulate the production of bone.

83. Implantation of BMP-2 in a collagen sponge induces new bone formation and can be used for the treatment of bony defects, delayed union, and non-union.

BMP-2 AS A BIOLOGIC

84. BMP-2 is not a device, but instead it is a biologic. *See* July 2009 American Medical Association Article and 2011 Stanford School of Medicine Article.

85. According to the FDA, "[a] 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service ActSec.351(i)1."Available http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

86. BMP-2 is a Bone-Morphogenetic Protein that is used to promote bone creation and remolding and falls under the definition of a biologic. *See* AMA article ("bone forming properties") and Stanford Article. BMP-2 differs from a medical device in that once implanted, it can only be removed days after surgery. If a patient had a complication due to BMP-2 and did not discover this complication until year after surgery, the patient could not have BMP-2 removed to reduce the complication because BMP-2 is so integrated into the patient's bone.

87. A patient has a right to determine what happens to his or her body and the preservation of that right requires that the patient be informed when a bone growth product, that causes irreversible harm, is placed in his or her body.

WHEN IS IT USED?

88. Recombinant human BMPs are used in orthopedic applications such as spinal fusions, non-unions, and oral surgery.

89. The bone graft contains two parts. The first is a solution of human bone growth protein or morphogenetic protein-2. This protein is found in the human body in small dosages and is important for the healing and formation of bones. The protein is genetically engineered to be utilized in the Infuse Bone Graft product, and it is employed for the stimulation of formation and growth in bones.

90. The second part of the bone graft is an absorbable collagen sponge.

91. Both components of the Infuse Bone Graft structure are used to fill the LT-Cage Lumbar Tapered Fusion Device. This chamber is intended to restore the deteriorated disc space to its original height.

92. FDA-approved use for the Infuse Bone Graft product is only for lower back surgery using an anterior lumbar interbody fusion (ALIF), a technique where the operation on the spine is conducted through the abdomen.

93. In addition, the Infuse Bone Graft product must be used in conjunction with Medtronic's LT-Cage. Use of BMP-2 without the LT-Cage is considered an "off-label" use.

CONTRAINDICATIONS OF USE

94. The FDA specifically warns against the use of Infuse in the cervical spine, citing reports of "life-threatening complications."

95. Any use of Infuse other than in lumbar spine surgeries with the LT-Cage is considered "off-label" use

96. Infuse should never be used on the skeletally immature patient, i.e., in patients less than 18 years of age or those with no radiographic evidence of epiphyseal closure.

97. Infuse should never be used in the vicinity of a resected or extant tumor.

98. Infuse should never be used in those patients known to have active infection at the surgical site.

RISKS ASSOCIATED WITH OFF-LABEL USE

99. When used in an off-label manner, patients may experience problems with pregnancy, including but not limited to: complications in fetal development; allergic reactions to titanium, bovine type I collagen, or bone morphogenetic protein–2; infection; the creation or intensification of tumors; liver or kidney disease; lupus or human immunodeficiency virus (HIV/AIDS); problems with radiation, chemotherapy, or steroids if a patient is malignant; paralysis; bowel and/or bladder dysfunctions; sexual disorders, including sterilization and incompetence; respiratory failure; excessive bleeding, and; death.

IV. THE REGULATORY PROCESS

100. The Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., established two separate approval processes for medical devices: Pre–Market Approval (PMA) and Pre–Market Notification.[1]

101. The FDA's PMA process is lengthy and involves extensive investigation by the FDA. The PMA application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before FDA approval can be obtained under this process. FDA regulations also require PMA applicants to submit copies of all proposed labeling for the device. 21

[1] *Fender v. Medtronic,* 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

C.F.R. § 814.20(b)(10). The FDA approves a PMA application only after extensive review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.[2]

102. In contrast, the FDA's Pre–Market Notification process is more abbreviated and involves less FDA oversight. This process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. Pre–Market Notification applicants must also submit their proposed labeling. 21 C.F.R. § 807.87. If the FDA determines that a device is substantially equivalent to a device that was on the market prior to the enactment of the MDA in 1976, the applicant is free to market the device.

103. BMP-2 received PMA (PMA number P000058) for the Infuse/BMP-2 Lumbar Tapered Fusion Device, which PMA provided for limited use with specific requirements for its use on individuals. See Medtronic Package Insert.

SCOPE OF THE PMA AND PRODUCT LABELING

104. The PMA for BMP-2 provided that the product may only be used in patients with the following characteristics:

d. Skeletally mature patient, AND

e. At levels L2-S1, AND

f. Confirmed degenerative disc disease (DDD), AND

g. Using only an open anterior or anterior laparoscopic approach, AND[3]

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[2] *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

[3] The anterior interbody fusion approach was developed because the risk of non-union (pseudarthrosis) is significantly higher in posterior approaches. The biggest risk factor for fusion surgery is non-union.

h. Six months of non-operative treatment prior to treatment with the device, AND

i. In combination with the metallic LT-CAGE.[4]

See Medtronic Package Insert, "INDICATIONS."

105. According to Medtronic's package insert for BMP-2/Infuse as well as other industry literature, the following risks are associated with the use of BMP-2/Infuse:

A. Male Sterility

B. Cancer

C. Increased progression of cancer

D. Suffocation of the cervical region

E. Bone fracture

F. Bowel/bladder problems

G. Loss of spinal mobility or function

H. Change in mental status

I. Damage to blood vessels and cardiovascular system compromise

J. Excessive bone mass blocking the ability to treat pain

K. Damage to internal organs and connective tissue

L. Death

M. Respiratory problems

N. Disassembly and migration of components

O. Dural tears

[4] Instrumented fusions involve hardware and are more stable fusions with a shorter recovery time than non-instrumented fusions.

P. Ectopic and exuberant bone formation

Q. Fetal development complications (birth defects)

R. Foreign body (allergic) reaction

S. Gastrointestinal complications

T. Incisional complications

U. Infection

V. Insufflation complications

W. Neurological system compromise

X. Non-union

Y. Delayed union

Z. Mal-union

AA. Change in curvature of spine

BB. Retrograde ejaculation

CC. Scars

DD. Tissue and nerve damage

EE. Itching

FF. Pain

GG. Hematoma

HH. Anaphylactic reaction

II. Elevated erythrocyte sedimentation rate

106. Injury Percentages:

j. Ectopic Bone Growth-63%

k. Inflammatory Neuritis-15%

l. Osteolysis/Subsidence-13%

m. Acute Swelling-7%

n. Retrograde Ejaculation-2%

o. 85% of time, BMP-2 implanted in off-label use

107. Not a single one of these risks in the last two paragraphs were ever explained to a single patient at Children's Hospital by Dr. Durrani.

108. BMP-2 was NOT approved by the FDA for use in the cervical and thoracic spine and BMP-2 was NOT safe or approved for use in children less than 21 years of age. These uses are considered "off-label."

"OFF-LABEL" USE

109. A use of a device is considered "off-label" if it is not approved under the Pre-Market Approval process OR cleared for such use pursuant to 21 U.S.C. § 360c(f) (also known as "the 510k premarket notification process").

110. Infuse can be implanted in an off-label manner in three ways:

p. Approach/position: Any approach other than an anterior approach;

q. Product: Failure to use LT-Cage (or any cage); mixing rhBMP-2 with other grafting products like Allograft or Autograft;

r. Discs: Use on multiple levels or on a level outside of L2-S1.

111. Dr. Durrani and the Hospitals in which he performed surgeries repeatedly used BMP-2 in these non-FDA-approved manners.

THE NON-COMPLIANCE WITH THE REGULATORY PROCESS

112. The PMA 000058 "Conditions of Approval" specifies the following condition: "Before making any change affecting the safety or effectiveness of the device, submit

a PMA supplement for review and approval by the FDA … [a] PMA supplement or alternate submission shall comply with applicable requirements under 21 C.F.R. 814.39[.]"

113. 21 C.F.R. 814.39 requires a PMA supplement pursuant to subsection (a)(1) for new indications of use of the device and pursuant to subsection (a)(6) for changes in components.

114. The PMA 000058 "Conditions of Approval" notes the post-marketing reporting requirement imposed by 21 C.F.R. 814.84, particularly "Identification of changes described in 21 C.F.R. 814.39(a)." Medtronic did not comply with this requirement relating to the intended uses and componentry.

115. The FDA can impose post-approval requirements in the PMA pursuant to 21 C.F.R. 814.82, and this fact results in the device being characterized as "restricted" pursuant to 21 U.S.C. § 360j(e) for purposes of 21 U.S.C. § 352(q). Section 352(q) states that any restricted device that is distributed or offered for sale with false or misleading advertising is "misbranded."

116. "Indications for use" is a necessary part of the PMA application and the "Indications for use" are required to be limited by the application. Any different use is inconsistent with the PMA.

117. A device that fails to meet the requirements of the PMA or 21 C.F.R. 814 is "adulterated" as defined by 21 U.S.C. § 351(f).

118. 21 C.F.R. 801.6 defines a misleading statement related to a DIFFERENT device contained in the label delivered with the device intended to be used will render the device to be used misbranded.

119. Medtronic did not apply for a PMA supplement, as required by the FDA generally and PMA 000058 specifically, for the off-label uses, nor did it provide warnings of the risks known about the off-label uses. All named Defendants in these cases knew about the occurrences of off-label use.

120. The PMA requires an application prior to marketing for new indicated uses by incorporating the federal requirements and explicitly reciting the text of 21 C.F.R. 814.39 and 814.84 and by specifically stating the range of indicated uses on the PMA.

V. MEDTRONIC

121. In or about 2001, Medtronic began preparing for the launch of two spinal fusion products, PYRAMID and INFUSE (BMP-2), which it projected would enjoy broad application with spinal surgeons and their patients on a nationwide basis.

122. Medtronic anticipated that both products would initially be limited in application.

123. Motivated by greed and a desire to gain competitive advantage in the marketplace, Medtronic began a course of conduct designed to broaden the application of both products by end-users. The course of conduct involved fraud, false statements, material misrepresentation, and deceit for the purpose of broadening the sales of these products beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

124. On or after July 2, 2002, Medtronic received notification that its Pre-Market Approval application for its BMP-2/Infuse bone graft products had been approved by the FDA. However, such approval was limited to the application of the device from the L4 through S1 levels. Further, the approval mandated the conduct of post-approval studies to evaluate the long-term performance of the BMP-2 bone graft and to study

the potential side effects and complications such as the promotion of tumors by the bone morphogenetic protein component of BMP-2. Other studies were conducted as well. See "Allegations against Medtronic in the Unsealed Mississippi False Claims Case."

125. Medtronic engaged in a fraudulent course of conduct designed to maximize its revenues from BMP-2, regardless of whether it would eventually be allowed to remain on the market.

126. One of the physicians Medtronic co-opted into its fraudulent scheme was a Thomas A. Zdeblick, M.D. Dr. Zdeblick was an orthopedic surgeon whose invention, the LT-Cage, was the only approved device to act as the delivery vehicle for BMP-2 into the body.

127. Dr. Zdeblick enjoyed a position within the scientific community as a Key Opinion Leader, and he was both a practicing orthopedic surgeon and professor at the University of Wisconsin.

128. In one of Dr. Zdeblick's first attempts to tout his LT-Cage and rhBMP-2, which would become the active ingredient in the ultimate Infuse/BMP-2 product, he encountered some drawbacks to his goal of promoting his and Medtronic's products, which arose from the policy of certain industry journals, including the journal *Spine*, which followed industry standards before printing peer-reviewed material. See article in the journal *Spine*, published in 2000.

129. Not only were the drawbacks related to industry publishing standards, but the National Consumer Health Information and Health Promotion Act of 1976 enacted certain provisions at 42 U.S.C. § 300u, et seq., whereby the Federal Government had

entered the field of medical research publication. Such standards promulgated by the Secretary of the predecessor to the U.S. Department of Health and Human Services required that applications for grants and contracts must be subject to "appropriate peer review." See 42 U.S.C. § 300u-1.

130. The drawbacks encountered with the peer-reviewed *Spine* article were as follows:

a. Attribution that the study was "sponsored by Medtronic Sofamor Danek, Inc.;"

b. The study was conducted under FDA regulations, and was "...designed as a prospective, multicenter, nonblinded, randomized, and controlled pilot study;" and

c. It was accompanied by a cautionary comment, or Point of View, which minimized the exuberance and import of the article.

131. In the article, BMP-2 was touted by Zdeblick and the co-authors as the potential realization of a dream of Dr. Marshall Urist, a revered pioneer in the industry and discoverer of BMP, where it closed with the following: "...it is encouraging to note that Marshall Urist's seminal observation made more than 34 years ago may finally come to clinical fruition."

132. In the Point of View, a Dr. John O'Brien of London questioned whether there could be long-term problems associated with the product. He treated Zdeblick's study with caution and pointed out that simple plaster of Paris has achieved the same or similar results more than 50 years prior. He posited that, "[p]erhaps vascularization...fixation procedures are as important as the biochemical composition of the 'filler.'"

133. Vascularization is achieved through removal of the disc material between two vertebral bodies and then the scraping of the surfaces of the vertebral bodies in a fusion procedure; fixation is the process of securing the motion segment through medical hardware. In other, if the alternative proposed by Dr. O'Brien proved to achieve equivalent or better results, Zdeblick and Medtronic's Infuse/BMP-2 products would be useless and unnecessary.

134. Certain efforts would follow in an attempt to alleviate the drawbacks encountered with the 2000 *Spine* journal article.

135. In 2002, Dr. Zdeblick was installed as the sole editor-in-chief of a medical journal known prior to his installation as the *Journal of Spinal Disorders*. Prior to his installation, the journal enjoyed a fourteen year history under the co-editorship of Dr. Dan Spangler and Dr. Tom Ducker. Once installed, Dr. Zdeblick successfully supplanted Drs. Dan Spengler and Tom Ducker and became the sole editor-in-chief, a position which would enable him to have greater control and would aid his participation in the fraudulent scheme.

136. During this same time period, Dr. Zdeblick also enjoyed a position on the associate editorial board of the medical journal *Spine*, the leading publication covering all disciplines relating to the spine.

137. In one of Dr. Zdeblick's actions as editor-in-chief, he set about re-purposing the journal in a way that would aid him in the furtherance of the fraudulent scheme through the streamlining of the publication process.

138. In furtherance of the fraudulent scheme, Dr. Zdeblick re-purposed the journal and renamed it the *Journal of Spinal Disorders and Techniques* (JSDT), announcing that

the new journal was "entering a new partnership with *Spine*." As part of this partnership, *Spine* would "continue to function as a broad-based scientific journal" tailored to both clinicians and scientists. However, the *Journal of Spinal Disorders and Techniques* would be directed solely to physicians in clinical practice.

139. Dr. Zdeblick's stated goal was "to provide a forum for up-to-date techniques…", and in furtherance of that goal, Dr. Zdeblick announced that his journal would publish Class II or better clinical articles but would "occasionally accept cutting edge articles with less than one year follow-up." To justify this streamlined process, Dr. Zdeblick claimed as his goal the ability of his journal "to keep up with the fast pace of progress in the treatment of spinal patients."

140. Arm-in-arm with Medtronic and others, Dr. Zdeblick would in short order abuse his position of trust as the editor-in-chief of JSDT.

141. In the October 2002 edition, JSDT published an article entitled, "Anterior Lumbar Interbody Fusion using rhBMP-2 with Tapered Interbody Cages." This article was co-authored by, among others, Curtis A. Dickman, M.D., who was a developer of Medtronic's PYRAMID plate and who has been paid significant sums by Medtronic through royalty agreements, consulting agreements, and education training and speaking agreements.

142. In addition to his interest in the PYRAMID plate, Dr. Dickman had assisted Medtronic in the approval process for Infuse/BMP-2. As part of the pre-approval hearing process, Dr. Dickman and his Barrow Neurological Associates Group of Phoenix, Arizona had submitted a letter to the meeting of the FDA's Orthopedics and Rehabilitation Devices Advisory Panel, which met on January 10, 2002. In that letter,

Dr. Dickman represented that "approval of BMP would provide a significant advance for patient outcome and satisfaction following spinal fusion."

143. In the October 2002 issue of JSDT touting the benefits of Infuse/BMP-2, Zdeblick and others failed to disclose their financial ties to Medtronic, though industry standards require such acknowledgement. Not only did Dr. Zdeblick fail to disclose that he profited from each and every surgery which Infuse/BMP-2 was used through rights in the exclusive delivery vehicle, his LT-Cage, but no reference whatsoever to their financial ties to Medtronic was made either by Dr. Zdeblick or Dr. Dickman.

144. For years, the recognized gold standard for spinal bone grafts has been the use of autogenous bone, or bone harvested from the patient's own iliac crest, or hip bone. Medtronic designed to have its Infuse/BMP-2 product supplant autogenous bone as the gold standard in the medical community, and utilized false statements, a fraudulent enterprise and the support of Federal funds to do so.

145. As part and parcel of Medtronic's fraudulent scheme, the October 2002 study was published in Dr. Zdeblick's journal three months after Medtronic received FDA approval for Infuse. As the article shows, it was actually received on March 28, 2002 or after Dr. Zdeblick had accomplished installment as the editor-in-chief, and was accepted by Dr. Zdeblick's journal for publication on July 30, 2002.

146. At the same time Dr. Zdeblick's journal was publishing the initial article on Infuse, Dr. Zdeblick was already finalizing and preparing for subsequent publication a follow-up article to tout Infuse potentially as the new gold standard. A second article, co-authored by Dr. Zdeblick and two other co-authors of the original article, was entitled

"Is Infuse Bone Graft Superior to Autograft Bone? An Integrated Analysis of Clinical Trials using the LT-Cage Lumbar Tapered Fusion Device."

147. This second article was published in Vol. 2 of 2003 and once again, there was no mention of Dr. Zdeblick's financial ties to Medtronic.

148. This second article would serve as the second covert advertisement for the Infuse product, and the article states that "the purpose of our analysis was to investigate the potential statistical superiority of Infuse bone graft to autograft…"

149. This second article went on to announce the July 2002 FDA approval of rhBMP-2.

150. This article included as an "acknowledgment" an expression of gratitude to the physicians "who provided patients for this study and to the clinic research group at Medtronic Sofamor Danek for their help in data collection and statistical analyses." However, the article still failed to advise the medical community that some or all of the authors reaching these conclusions touted as monumental had direct financial interests tied to those conclusions.

151. Rather, the failure to report these clear conflicts of interest on the part of those holding positions of trust both within the medical community and over patients was part of Medtronic's fraudulent enterprise. However, unchecked by appropriate peer review, Medtronic was able to systematically accomplish their goals.

152. In its 2003 Annual Report, and without recognizing that Zdeblick was being paid by Medtronic, Medtronic cited to Zdeblick's 2003 as reporting that Infuse "…may become the new gold standard in spinal fusion surgery."

153. By its 2006 Annual Report, if not earlier, Medtronic had removed all doubt, declaring that after its introduction in 2002, "Infuse Bone Graft quickly became the gold standard for certain types of lumbar fusion."

154. Medtronic's fraudulent scheme was successful and resulted in a revenue stream ranging from 700 to 900 million dollars per year.

155. It has been reported that around the same time these stories about Infuse were published, editors at the Spine Journal began receiving complaints from doctors around the country who were pointing out contradictions between papers published by doctors with financial ties to Medtronic and other data involving Infuse complications.' See *Journal Sentinel* article of John Fauber.

156. Through the use of these sham consulting, royalty and education/training agreements with its physician agents in this fraudulent enterprise, Medtronic has reaped windfalls in the billions of dollars. Medtronic has used this fraudulent enterprise and civil conspiracy to drive its vast profits and enhance its market position beyond that which it would have realized without engaging willfully, knowingly and potentially deliberate, conscious, or reckless indifference in the fraudulent enterprise and fraudulent concealment. See Mississippi case.

157. Defendants had full knowledge of all these facts pertaining to Medtronics.

VI. FDA PUBLIC HEALTH NOTIFICATION

158. On July 1, 2008 the FDA issued a Public Health Notification entitled "Life-Threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion."

159. This notification was sent to health care practitioners all across the United States warning of the complications associated with BMP-2, specifically when used in the cervical spine.

160. In the notification the FDA stated they received at least 38 reports of complications during the prior four years with the use of BMP-2 in cervical spine fusions.

161. The complications were associated with swelling of the neck and throat areas, which resulted in compression of the airway and/or neurological structures in the neck.

162. Some reports describe difficulty swallowing, breathing or speaking and severe dysphagia following cervical spine fusion using BMP-2 products had also been reported.

163. The notification further stated that, "since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

164. The Notification further emphasized the importance of fully informing patients of these potential risks and said that patients treated with BMP-2 in the cervical spine should know:

s. The signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area

t. That they need to seek medical attention immediately at the first sign of an airway complication

u. That they need to be especially watchful 2-14 days after the procedure when airway complications are more likely to occur

v. rhBMP-2 (contained in Infuse Bone Graft) has received pre-market approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease at one level from L2-S1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury

165. Additionally, BMP is not approved in any manner for use in patients who are skeletally immature (<18 years of age) or pregnant.

166. Dr. Durrani and the Hospitals ignored ALL of these warnings and used BMP-2 in cervical spine surgeries, children, and those with known compromising factors such as osteoporosis, smoking, and diabetes.

167. Furthermore, the Notification stated that the FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

168. The Hospitals that allowed Dr. Durrani to use BMP-2 in their facilities failed to report any complications resulting from his use of BMP-2.

VII. SENATE FINANCE COMMITTEE REPORT

169. Medtronic's actions did not go unnoticed, and in June of 2011 the Senate Finance Committee began an investigation into the fraudulent actions of Medtronic.

170. Medtronic produced more than 5,000 documents pertaining to 13 different studies of BMP-2 for the investigation.

171. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into Medtronic, which revealed questionable ties between the medical technology company and the physician consultants tasked with testing and reviewing Medtronic products.

172. The investigation revealed that Medtronic employees collaborated with physician authors to edit and write segments of published studies on BMP-2/Infuse without publicly disclosing this collaboration.

173. These fraudulently-produced studies may have inaccurately represented BMP-2's risks and may have placed added weight on the side effects of alternative treatments.

174. The Senate investigation further found that Medtronic also maintained significant, previously undisclosed financial ties with physicians who authored studies about BMP-2, making $210 million in payments to physicians over a 15-year period.

175. Senator Baucus stated, "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. Patients everywhere will be better served by a more open, honest system without this kind of collusion."

176. Senator Grassley stated, "The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and the studies they feature. These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It's in the

interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

177. Major findings of the investigation include:

a. Medtronic was involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's role in authoring or substantially editing these articles was not disclosed in the published articles. Medical journals should ensure that any industry role in drafting articles or contributions to authors is fully disclosed.

b. Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with BMP-2/Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

d. Medtronic officials inserted language into studies that promoted BMP-2 as a better technique than an alternative by emphasizing the pain associated with the alternative.

e. Documents indicate that Medtronic prepared one expert's remarks to the FDA advisory panel meeting prior to BMP-2 being approved. At the time,

the expert was a private physician but was later hired to be a vice president at Medtronic in 2007.

f. Medtronic documents show the company successfully attempted to adopt weaker safety rules for a clinical trial studying BMP-2 in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

VIII. YODA STUDY

178. In response to the various controversies surrounding BMP-2/Infuse, including a June 2011 article in the journal *Spine*, the Yale University Open Data Access (YODA) team reached an agreement for Medtronic to provide full individual participant data from all their trials of rhBMP-2 and allow unrestricted independent re-analysis of this data.

179. The YODA study involved research teams at two universities – the University of York and the Oregon Health and Science University.

180. The review focused exclusively on the use of rhBMP-2 in patients undergoing spinal fusion surgery for treatment of degenerative disc disease, spondylolisthesis, or any other relevant spinal condition.

181. The three main objectives of the study were: 1) to examine the potential benefits of BMP-2, 2) to examine the potential harms of BMP-2, and 3) to assess the reliability of the published evidence base.

182. Medtronic submitted data from 17 studies, including 12 randomized controlled trials (RCTs).

183. In total, the YODA study analyzed the data from 1,409 participants.

184. Though the results showed moderate success with fusions as a result of BMP-2, the study found that BMP-2 results in several different complications including: arthritis, implant-related events, retrograde ejaculation, wound complications, and neurological, urogenital, and vascular events.

185. In regard to the alleged tampering with the peer-reviewed studies by Medtronic, the YODA study found that only two out of twenty peer-reviewed journal publications reported a comprehensive list of all adverse events that occurred during the studies.

186. Furthermore, the way in which adverse event data was presented in the literature was inconsistent, and the rationale for presenting some adverse events but not others was rarely clear.

187. The study concluded that for the period up to 24 months after surgery, treatment with BMP-2 increases the probability of successful fusion (according to Medtronic definitions and reports, which the study noted "were subjective so it is not possible to confirm whether reported successful fusions truly were successful" see YODA Study, p. 35) but this does not translate to clinically meaningful benefits in pain reduction, function, or quality of life. The small benefits in these outcomes observed from six months onward come at the expense of more pain in the immediate post-operative period and a possible increased risk of cancer.

188. Even more relevant to the case against Dr. Durrani and the Hospitals is the YODA study's conclusion that, "[i]t is very important that these findings are expressed clearly and discussed with patients so that they can make informed choices about the type of surgery they would prefer." *Id.*

189. The University of Oregon Study determined that Infuse/BMP-2 is not better than Autograft, while the University of York study determined that Infuse/BMP-2 offers only a slight and not statistically significant advantage over Autograft.

190. The YODA study concluded that Medtronic "misrepresented the effectiveness and harms through selective reporting, duplicate publication, and underreporting."

191. Adverse event categories such as heterotopic bone formation, osteolysis, and radiculitis were not included in participant databases or internal reports; therefore, the safety profile was not fully assessed.

192. The YODA study further concluded that Medtronic was involved in drafting, editing, and shaping the content of medical journal articles on Infuse/BMP-2 authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles.

193. Medtronic paid a total of approximately $210 million to the physician authors of Medtronic-sponsored studies on Infuse from November 1996 through 2010 for consulting, royalty and other arrangements.

194. An email exchange showed that a Medtronic employee recommended against publishing a complete list of adverse events or side effects possibly associated with Infuse in a 2005 *Journal of Bone and Joint Surgery* article.

195. Medtronic officials inserted language into studies that promoted Infuse as a better technique than an alternative procedure by overemphasizing the pain associated with the alternative procedure.

196. Medtronic's actions violated the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. See United States Senate Committee on Finance, October 2012.

197. Infuse was intended for a single level anterior lumbar interbody fusion performed with all three components in a specific spinal region. The three components are a tapered metallic spinal fusion cage (NOT PLASTIC), a recombinant human (BMP) bone Morphogenetic Protein, and a carrier/scaffold for the BMP and resulting bone. The Infuse product is inserted into the LT-CAGE Lumbar tapered Fusion Device component to form the complete Infuse Bone Graft/LT–Cage Lumbar Tapered Fusion Device. These components must be used as a system. The Infuse Bone Graft component must not be uses without the LT-Cage Lumbar Tapered Fusion Device component.

198. BMP-2 is not supposed to be used in minors.

199. BMP-2 is not supposed to be used with smokers and diabetics because of vascular slowing.

200. BMP-2 should not be used with women in child bearing years.

201. BMP-2 is contraindicated for patients with a known hypersensitivity to rhBMP-2 and should not be used in the vicinity of a resected or extant tumor, in patients with active malignancy, or in patients undergoing treatment for a malignancy.

IX. DR. DURRANI AND BMP-2

202. Despite all of these warning signs, Dr. Durrani, with the full knowledge of the Defendants, continued to use BMP-2 in ways not approved by the FDA, or in an "off-label" manner.

203. As early as 2007, Dr. Durrani and UC Health knew there were issues with BMP-2 because insurance companies such as Anthem were refusing to pay for BMP-2.

204. Medtronic provided in writing to Dr. Durrani and CAST the approved uses for Infuse/BMP-2.

205. However, Dr. Durrani and the Defendants continued to use BMP-2 in off-label ways, including but not limited to:

a. Using BMP-2/Infuse in children, despite Medtronic specifically requiring it be used only in "skeletally mature patients;"

b. Using it outside the L2-S1 level of the spine;

c. Ignoring the requirement that BMP-2/Infuse only be used for Grade 1 spondylolisthesis or Grade 1 retrolisthesis;

d. Not requiring at least six months of non-operative treatment prior to the use of BMP-2/Infuse;

e. Using BMP-2/Infuse without the required cage;

f. Not using the "carrier scaffold" in conjunction with BMP-2/Infuse as required;

g. Using BMP-2/Infuse without proper training despite Medtronic's warning, "Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience."

206. Dr. Durrani was a paid consultant for Medtronic.

207. According to Dr. Durrani's own deposition testimony in several cases, Medtronic required one of their representatives to be present in the operating room when its product BMP-2/Infuse is used.

208. Because Medtronic representatives were present in these surgeries, Medtronic knew when Dr. Durrani used BMP-2/Infuse outside the approved uses according to Medtronic's own guidelines.

209. Dr. Durrani was encouraged by Medtronic to obtain peer review and published studies from Medtronic sales representatives to support his use of BMP-2/Infuse.

210. Dr. Durrani was encouraged by Medtronic to be an advocate for his patients and describe how BMP-2/Infuse technology can benefit them.

211. When asked how he got his Medtronic grant, Dr. Durrani responded, "You apply to the Medtronic's corporate and say this is what we want to do, like everybody else in the country applies, and then they come and evaluate the thing and say, "Okay, we think it's worthy. We'll give you the grant."

212. In regard to his role as a Medtronic consultant, Dr. Durrani stated, "If there are certain products that they help us in developing, then they will come to us for a certain consultant role for a certain product development."

213. Dr. Durrani also stated, "I was involved in the development of the minimally invasive spine instrumentation."

214. Dr. Durrani gave conflicting reports on his financial relationship with Medtronic.

215. In a deposition, when asked when his relationship with Medtronic began, Dr. Durrani responded "2000-it's 2003, '04. Something in that category. I'm not sure. It's on the Medtronic website. You can go look at it."

216. Medtronic's website has no information regarding their relationship with Dr. Durrani.

217. In another deposition, Dr. Durrani stated he began his relationship with Medtronic in "2005 or '06."

218. Dr. Durrani also gave conflicting reports on how much compensation he received from Medtronic for his consultation services.

219. In one deposition, Dr. Durrani stated in response to an inquiry as to how much payment he received, "It's a standard compensation. Again, it's on the website, how much they've paid us."

220. Again, this information is not available on the Medtronic website.

221. In another deposition, when asked if he received income from Medtronic, Dr. Durrani replied, "No, I don't."

222. When questioned further if he received a fee as a consultant, he stated, "If you do a work, there is a contractual obligation that they have to pay you. As I told you in my last deposition, they did declare it on their website, so you can actually go on the website and see how much they paid."

223. In another deposition, Dr. Durrani stated that he received, "less than $10,000 in ten years" from Medtronic.

224. An email dated July 30, 2008 from Medtronic Senior Product Manager Katie Stamps to Dr. Durrani states that she "is in the process of working on the renewal of your [Dr. Durrani's] consulting agreement." As stated, this information is not available on Medtronic's website, nor is any information relating to Dr. Durrani's role as a consultant for Medtronic.

225. A CCHMC packet relating to its Orthopedics department indicated that Dr. Durrani received $60,000 in grants, contracts, or industry agreements from Medtronic Sofamor Danek in FY 2008.

226. Financial information discovered concerning Dr. Durrani's relationship with Medtronic was found in Dr. Durrani's biography on the website for the Orthopaedic & Spine Institute, which Dr. Durrani currently operates in Pakistan. The biography states that "Dr. Atiq Dr. Durrani has also received the Clinical Spine Fellowship Grant by the Department of Orthopaedic Surgery which was funded by Medtronic Sofamor Danek with a budget of $59,170 per year." See http://www.osi.com.pk/doctor/dr-atiq-Dr.Durrani-md/.

227. When a request was made to Medtronic regarding its affiliation with Dr. Durrani, the Medtronic Supplier Relations Team stated that Dr. Durrani's "name [is] not listed in our system."

228. Medtronic further responded to the Deters Law Firm's request that the firm would need a "Vendor I.D. Number," which neither Medtronic nor any other party has provided.

229. David Rattigan, was Dr. Durrani's main Medtronic representative from Bahler Medical.

230. David Rattigan and Medtronic have the same lawyer. Despite the Deters Law Firm's willingness to cooperate in scheduling the date for a deposition, they have refused until recently. Mr. Rattigan's deposition was taken June 5, 2015.

231. In summary, clients of the Deters Law Firm, with the full knowledge and intentional consent of all Defendants, became unsuspecting experiments for real world testing of

Medtronic hardware and BMP-2, by and through Dr. Durrani and CAST, who had secret financial connections to Medtronic, improper motives, and submitted false claims. The government paid for many of these improper and unregulated experiments as a result of the false claims made by Dr. Durrani, with the knowledge of Medtronic, under the veil of "medically necessary" surgeries.

232. Despite repeated requests, Medtronic has refused to cooperate in providing any requested information and is actively downplaying their connections to Dr. Durrani.

X. THE DEFENDANTS AND BMP-2

233. The purpose of the background information on the following Defendants and BMP-2 concerning other hospitals is to show the egregious methods, which upon information and belief were used at all hospitals.

234. The Defendants allowed and encouraged these practices by Dr. Durrani for the sole purpose of money and greed.

235. David Rattigan was always present in Dr. Durrani's operating rooms as a representative of Medtronic.

236. David Rattigan's sole job was to deliver the BMP-2/Infuse to the Hospitals and make sure that it was inserted correctly into the patient.

237. David Rattigan's presence in the OR further supports the Defendants awareness of Dr. Durrani's fraudulent use of BMP-2/Infuse.

238. **Informed Consent for Surgical or Medical Procedure and Sedation:**

It is the responsibly of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

a. The explanation of the procedure

b. The benefits of the procedure

c. The potential problems that might occur during recuperation

d. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.

e. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.

f. The likelihood of achieving satisfactory results

Completion of the "Consent to Hospital and Medical Treatment" form to examine and treat is NOT sufficient as consent to perform a surgical procedure, invasive procedure, or for medical regimens of substantial risk or that are the subject of human investigation or research.

239. The Defendants had the responsibility to carry out these consent rules.

240. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

241. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

242. Dr. Durrani is a consultant for Medtronic.

243. Defendants did not inform Plaintiffs of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

244. Medtronic, provided in writing to Dr. Durrani the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

245. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

246. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

247. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

248. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

249. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

250. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

251. Dr. Durrani and Children's Hospital personnel did not disclose to Plaintiffs their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

252. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

253. Defendants did not inform Plaintiffs that Dr. Durrani used Infuse/BMP-2 in his surgeries.

254. Plaintiffs would not have allowed BMP-2 to be used by Dr. Durrani in his surgery in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

255. Plaintiffs would not have consented to the use of BMP-2 in Plaintiff's body if informed of the risks by Dr. Durrani or any Children's Hospital personnel.

256. The written informed consent of Dr. Durrani signed by Plaintiffs lacked the disclosure of Infuse/BMP-2's use in his procedures.

257. Plaintiffs never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani or any Children's Hospital personnel.

258. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

259. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

260. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

261. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

262. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

INFUSE/BMP-2

263. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

264. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

265. Dr. Durrani is a consultant for Medtronic.

266. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

267. Medtronic, provided in writing to Dr. Durrani and CAST the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

268. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

269. BMP-2 is neither safe nor approved for use on children less than twenty one (21) years of age.

270. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

271. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

272. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When

nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

273. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

274. Dr. Durrani, CAST staff and employees, and Journey Lite personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

275. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

276. Plaintiff was not informed by Defendants that Dr. Durrani used Infuse/BMP-2 in her surgery.

277. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in her surgery in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

278. Plaintiff would not have consented to the use of BMP-2 in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any Journey Lite personnel.

279. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in her procedures.

280. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, CAST staff and employees, or any Journey Lite personnel.

281. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

282. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

283. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

284. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

285. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

PUREGEN

PUREGEN BACKGROUND

286. PureGen Osteoprogenitor Cell Allograft (PureGen) is a highly concentrated, pure population of Early Lineage Adult (ELA) stem cells that originates in bone marrow and is collected from live, healthy donors.

287. PureGen is harvested from living human beings under the Stem Cell Collection Program administered by the Food and Drug Administration (FDA) and is defined as both a "biologic" by 42 U.S.C. 351(i) and a "drug" as defined by U.S.C. 321(g).

288. PureGen's purpose was to facilitate bone fusion by mimicking the regenerative environment of youthful tissues by increasing the concentration of stem cells available to repair tissue and build bone.

289. When used off-label, as Dr. Durrani often did, biologic bone allograft frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord.

290. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

291. Alphatec Spine, Inc. is a corporation under the laws of California, and jointly developed and distributed PureGen in the State of Ohio.

292. Alphatec Holdings, Inc. is a holding corporation formed under the laws of Delaware with no operations separate from the holding of other companies which owns Alphatec Spine, Inc.

293. Dirk Kuyper was President and CEO of Alphatec Holdings, Inc. from February 2007 to August 2012.

294. Parcell Laboratories, LLC is organized under the laws of Delaware and jointly developed Puregen.

295. Alphatec and Parcell co-developed the product "PureGen", and both expected PureGen would be initially limited in application.

296. PureGen is produced and distributed by Alphatec Spine, LLC, a division of Alphatec Holdings.

297. PureGen was entered into 3 clinical trials by Alphatec on or around February 9, 2011 which were scheduled to last until September of 2013.

298. The study population were 50 male/female subjects 18 years and older suffering from symptoms of cervical degenerative disc disease in one to four contiguous levels between C3 and T1.

299. The clinical trial required:

a. Inclusion

i. Age over 50

ii. Side-by-side use of Puregen and Autologous bone in the same patient for radiographic comparison

iii. Symptomatic lumbar degenerative disc disease in up to 2 contiguous levels between L1 and S1

iv. Subjects with back and/or leg paint indicated for posterior stabilization with or without decompression at any level and posteriolateral fusion

v. Unresponsive to conservative treatment for at least 6 months

vi. Radiographic evidence of primary diagnosis

b. Exclusion:

vii. No healthy volunteers permitted

viii. More than two levels requiring posteriolateral fusion (PLF)

ix. Spondyliosis greater than Grade 1

x. Prior failed fusion surgery at lumbar level(s)

xi. Systemic or local infection in the disc or cervical spine, past or present

xii. Active systemic disease

xiii. Osteoporosis, Osteomalacia, or other metabolic bone disease that would significantly inhibit bone healing

xiv. Use of other bone graft, Bone Morphogenic Protein (BMP), or bone graft substitutes in addition to or in place of those products specified

xv. BMI greater than 40

xvi. Use of post-operative spinal cord stimulator

xvii. Known or suspected history of alcohol and/or drug abuse

xviii. Involved in pending litigation or worker's compensation related to the spine

xix. Pregnant or planning to become pregnant during the course of the study

xx. Insulin-dependent diabetes mellitus

xxi. Life expectancy less than duration of study

xxii. Any significant psychological disturbance that could impair consent process or ability to complete self-assessment questionnaires

xxiii. Undergoing chemotherapy or radiation treatment, or chronic use of oral or injected steroids or prolonged use of non-steroidal anti-inflammatory drugs

xxiv. Known history of hypersensitivity or anaphylactic reaction to dimenthyl sulfoxide (DMSO).

300. All 3 clinical trials were "Terminated" before any results were produced.

301. Alphatec and Parcell saw this limited approval for clinical trials as an opportunity to market PureGen without premarket approval, 510K clearance, an exception to the Food Drug and Cosmetic Act, meeting the humanitarian device exception, investigational new drug (IND) application, or other permission to market PureGen, all in violation of the Food Drug and Cosmetic Act.

302. Alphatec and Parcell began a course of conduct designed to expand the application of PureGen by end users in excess of the approved clinical trial of PureGen. This course of conduct utilized fraud, false statements, material misrepresentation, and deceit in order to broaden the sales of PureGen beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

303. The Food and Drug Administration (FDA) conducted an inspection of Parcell Laboratories between February 9-14, 2011.

304. After the inspection, the FDA responded quickly to the unlicensed marketing of the device PureGen by warning that PureGen was not the subject of an IND application nor a valid biologics license with a letter dated June 23, 2011.

305. The letter stated that the cells used in the production of PureGen were human cells, tissues, or cellular and tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d).

306. Based on this analysis, the FDA determined that PureGen was a drug and biological product as defined in the Federal Food, Drug and Cosmetic Act.

307. According to the Public Health Service Act, a valid biologics license is also required to introduce a biologics device to the market.

308. Alphatec Spine did not acquire a valid biologics license to enter a biologics product into interstate commerce, in violation of 21 U.S.C. 355(a); 42 U.S.C. 262(a).

309. The FDA stated that PureGen, "does not meet all of the criteria in 21 CFR 1271.10(a) and therefore is not regulated solely under section 361 of the Public

Health Service Act and the regulations in 21 CFR Part 1271. Specifically, the product does not meet the criterion in 21 CFR 1271.10(a)(4)(ii)(b) because the product is dependent on the metabolic activity of living cells for its primary function."

310. As a result, a valid biologics license was required, which was never obtained by Alphatec or Parcell labs in regards to PureGen. Defendants knew all this.

311. Given this lack of a valid biologics license, the FDA determined that the marketing of PureGen violated both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.

312. In a statement to the press approximately a week after receiving the FDA Letter, Alphatec President Dirk Kuyper stated, "Both Alphatec Spine and Parcell Laboratories are fully committed to work closely and collaboratively with the FDA to address the questions related to the PureGen Product. We look forward to discussing the PureGen product with the FDA and sharing our clinical outcomes to date." See article "Alphatec comments on FDA's letter regarding PureGen product for spinal fusion procedures", Spinal News International, July 28, 2011, attached as Exhibit E.

313. No such cooperation by Alphatec and Parcell labs occurred and no clinical outcomes were shared with the FDA as all clinical trials of PureGen were "Terminated" and no data was released as to the findings.

314. In fact, Alphatec and Parcell responded to this letter by continuing to market PureGen in an unlicensed manner until Alphatec finally acknowledged the

letter in or around February 2013, almost two years after receiving the letter, by stating it disagrees with the FDA's classification of PureGen as anything other than a tissue product – despite the clinical trial approval listing PureGen as "Biological: PureGen Osteoprogenitor Cell Allograft".

315. Furthermore, according to sales representative, Thomas Blank, Alphatec falsely informed distributors of PureGen that they "resolved" the issues addressed in the FDA letter, did not have to take PureGen off the market and it was "ok" for their distributors to continue marketing and selling PureGen.

316. Despite the approval for the clinical trial of PureGen which limited enrollment to 50 patients, Alphatec advertised in its 2012 Annual Report that PureGen had been implanted in over 3,500 patients.

317. PureGen further stated that it had been placed in these 3,500 patients with "no adverse events related to the product", despite no study, statistics or information to back up such a claim.

318. This 2012 annual report also identified PureGen as a biologic.

319. In the First Quarter of 2011, Alphatec Spine attributed part of its 40.9% increase in revenue to the PureGen product. See Becker's Spine Review, Alphatec Spine Reports $49.7M in Q1 Revenue, 40.9% Increase, May 5, 2011, attached as exhibit H.

320. Eventually, after PureGen had been unlawfully implanted in thousands of patients, Alphatec and Parcell conceded that PureGen is a tissue product and a biologic and stopped shipping PureGen in February of 2013.

PUREGEN AND OHIO LAW

321. It is the position of the Deters Law Firm that the distribution and use of PureGen by Dr. Durrani, Evolution Medical, Alphatec Spine, Inc., and upon Information and Belief Journey Lite is in violation not only of Federal Law as outlined in the FDA's letter, but Ohio State Law as well.

322. Ohio Revised Code 3715.65(A) states that "No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040 (1938), 21 U.S.C.A. 301". Defendants violated this provision.

323. A "New Drug" is defined as "Any drug the composition of which is not generally recognized among experts by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof." Ohio Revised Code 3715.01(9)(a).

324. PureGen's status as a Biologic further supports the classification of a drug under the FDA and Ohio Law: "A "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)). Additional interpretation of the statutory language is found in 21 CFR 600.3. Biological products also meet the definition of either a drug or device under Sections 201(g) and (h) of the Federal Food, Drug, and

Cosmetic Act (FD&C Act)." See http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm.

325. It is the position of the Deters Law Firm that PureGen is a drug as defined in ORC 3715.01 and that its distribution before FDA approval was in violation of ORC 3715.65(A). The Defendants with full knowledge and intent violated this statute.

PUREGEN AT THE HOSPITALS

326. Upon information and believe it is believed that Dr. Durrani used Puregen at Journey Lite in the same manner that PureGen was used at WCH.

327. Upon information and believe it is believed that Dr. Durrani was taking Puregen from WCH and using it at Journey Lite.

328. Plaintiff's have repeatedly requested itemized billing to confirm its use but have not received from Defendants.

329. On October 10, 2011, UC Health began purchasing PureGen from Alphatec. Thomas Blank was an employee of Innovative Medical Consultants, LLC and a sales representative, seller, marketer, and distributer of PureGen for the Northern Kentucky/Cincinnati area.

330. In his professional capacity, Thomas Blank was present during most, if not all, of the surgeries at issue where PureGen was secretly implanted into various Plaintiffs without informed consent or permission.

331. Thomas Blank worked directly with Alphatec Spine, Inc. and Defendants in the marketing and distribution of PureGen.

332. Additionally, Thomas Blank is a shareholder in Alphatec Spine, Inc.

333. On May 10, 2012 Evolution Medical, LLC, a physician owned distributorship (POD), owned in part (at least 40%) by Dr. Durrani and incorporated in Delaware, received a Kentucky Certificate of Authority.

334. Around this time, Thomas Blank began to work with Evolution Medical in the marketing and distribution of PureGen, in addition to his dealing with Alphatec Spine, Inc.

335. On July 20, 2012, UC Health with the full knowledge and consent of Defendants began purchasing PureGen from Evolution Medical, LLC.

336. The purchase of PureGen, the logistics of the billing, the bills of lading, the receiving and handling of PureGen for West Chester Hospital was handled by UC Health Purchasing.

337. The Defendants tracked West Chester/UC Health's purchases of PureGen from Evolution medical.

338. Specifically, Thomas Blank would provide the materials from Alphatec related to the use and approval of PureGen to Dwayne Brown on behalf of UC Health, who would request PureGen based on the amounts requested by Dr. Durrani and other doctors who used the product.

339. After the UC Health reps approved the use of PureGen, Thomas Blank and his associate Toby Wilcox would order the product, typically in bulk, and draft the requisite billing documents.

340. The PureGen ordered would be stored on site at WCH in the freezer of the operating rooms.

341. In addition to Dr. Durrani, other doctors at WCH used PureGen, including Dr. Chunduri, Dr. Curt and Dr. Shanti.

342. Defendants would purchase and allow these doctors to use a substance not approved by the FDA in patients without their informed consent.

343. Though WCH and UC Health do have patients fill out "informed consent" forms, no mention of PureGen or its non-FDA approved status is mentioned on these forms.

DR. DURRANI AND PUREGEN

344. In one of the few depositions taken of Dr. Durrani before his flight from the country he stated that PureGen is "essentially stem cells" and that he "used to use [PureGen] for a certain amount of time." Deposition of Dr. Durrani in *Brenda Shell v. Durrani*, p. 25-26, attached as Exhibit N.

345. This "certain amount of time" was approximately 3 years between 2010 and 2013, all while PureGen remained unapproved by the FDA.

346. Though downplaying his involvement with PureGen, Dr. Durrani, through his illegal POD Evolution Medical, distributed PureGen to West Chester/UC Health with the full knowledge and consent of Defendants.

347. Dr. Durrani and his Evolution Medical co-owner Toby Wilcox and Defendants, knew the Department of Health and Human Services and the United States Senate Finance Committee has released reports on dangers of Physician-owned entities, notably Physician-owned Distributorships (POD's).

348. Dr. Durrani and Toby Wilcox's actions through Evolution Medical violated the Anti-Kickback Statute 42 U.S.C. 1320 and Stark Law 42 U.S.C. 1395.

349. Compliance with the Anti-Kickback Statutes is a condition of receiving payment from a Federally-funded healthcare program, and most private insurers have a parallel conditional requirement.

350. The Anti-Kickback Statute prohibits the payment and receipt of kickbacks in return for either procuring or recommending the procurement of a good, facility, or item to be paid in whole or in part by a federal healthcare program. 42 U.S.C. 1320a-7b(b).

351. In violation of 45 C.F.R. 46, and in furtherance of the scheme to feign avoidance of the anti-kickback statutes, Dr. Durrani, CAST, Alphatec and the Defendants experimented on patients by using PureGen in unapproved manners, without the informed consent of the patients, and subsequently billing their health insurance companies all while concealing the true nature of their actions.

352. Dr. Durrani also had connections with Alphatec as his personal calendar indicates meetings with Dirk Kuyper, President and CEO of Alphatec in 2008.

353. Dr. Durrani experimentally used Puregen bone graft in twenty cervical surgeries, along with as many as 72 thoracic, cervical, and lumbar surgeries, ignoring the limited uses it was approved for in the clinical trials.

354. Dr. Durrani, through his POD Evolution Medical, was essentially "double dipping" in his dealings with PureGen.

355. Dr. Durrani would sell WCH and the other hospitals the PureGen through Evolution Medical and then use and bill for the PureGen in his surgeries.

356. Dr. Durrani and Defendants knew such an arrangement was either unethical and illegal (though still not disclosing the use of PureGen) by having the patients sign an Acknowledgement of Potential Conflict of Interest form.

357. WCH and Defendant also benefited from this arrangement by up charging patients for the PureGen after purchasing it from Evolution Medical and Dr. Durrani.

358. At all times relevant, Dr. Durrani and Defendants was in exclusive control of the amount and ratio of Puregen bone graft that was experimentally implanted into patients.

359. PureGen was and remains unapproved by the FDA for use in humans without an Investigation New Drug ("IND") or experimental informed consent of the patient.

360. Dr. Durrani and Defendants did not receive experimental informed consent from patients, nor did he verify that an IND was obtained.

361. The basic "Informed Consent Forms" Dr. Durrani and CAST did have patients fill out made no mention of PureGen or the fact a non-FDA approved product was being implanted in their body.

362. In fact, Dr. Durrani and Defendants would even conceal the use of PureGen by intentionally withholding it from the billing records, noting on one Pre-Op Code sheet "Do Not Bill" twice in regards to PureGen.

363. Implanting Puregen in any part of the spinal canal without FDA clearance, proper trials, and patient consent is reckless battery and violates the Hippocratic Oath's statement "I will prescribe regimens for the good of my patients according to my ability and my judgment and never **do harm** to anyone." It is criminal.

PUREGEN AND OUR CLIENTS

364. What follows are just a few examples of the damage caused Dr. Durrani and the Defendants deceptive and fraudulent use of PureGen in Deters Law Office clients without their consent.

365. A majority of these surgeries occurred AFTER the FDA inspection and subsequent warning on the non-FDA approved status of PureGen.

366. Following the cervical surgeries in which Puregen was implanted, the patients' pain became far worse and more extreme.

367. The patients attest to difficulty with swallowing unthickened liquid, medications in pill form, routine saliva, and food.

368. Many patients describe a choking sensation felt on a daily basis when swallowing and changes to the tone and audibility of their voice, along with a chronic cough.

369. Following the thoracic and lumbar surgeries, patients attest to increased spinal pain, difficulty with ambulation, numbness and tingling in lower extremities, decreased flexibility.

370. Below are some of the clients experiences since having the Puregen implanted:

371. "I have severe low back pain, stiffness, decreased range of motion and tenderness. Pain radiating to left posterior thigh and right/left lumbar area. Onset months ago after surgery." – William Hayes

372. "Constant, irritating pain, less intense but still present. Even after two surgeries, I continue to have limited use of my left leg. The pain is ever-present. I am easily fatigued and have severe pain after brief tasks such as cooking dinner, preaching a sermon, even making a bed. Bending over is so painful and produces such instability that my family helps put on my socks and shoes. I require a cane for ambulation, due to left leg weakness and limited range of motion." – Darrell Earls

373. "Severe spin in my neck, arm, shoulder blades. Pressure on my throat making it unbearable to swallow meds and food. Loss of range of motion in my neck and stiffness

in back. The pain is so severe that I can no longer sleep laying down. I have to sleep sitting up. The pain in my neck is unbearable most days. The pain runs between my shoulder blades into my chest and in my throat and side of my neck." - Duane Pelfrey

374. "I feel I have lost a lot of the flexibility in my neck and back. I have lower back pain, tightness in neck and shoulders, and have a hard time lifting/standing for long periods of time. When I bend over, I have a hard time straightening back up to an upright position." - Dana Conley

375. "Low back pain radiating into bilateral hips, buttocks, legs and feet. Bilateral leg weakness. Numbness in left foot and toes. Bilateral buttock and posterior thigh muscle spasms. Burning sensation in right abdomen that radiates around to back. My post-surgery MRI and CT scan showed bony overgrowth into the foramen and into the canal on left at L5-S1." - Julie Martin

376. "I experience pounding headaches that are far worse than anything prior to surgery. Left leg is numb, painful and swollen, muscle spasms occurring in hip and bilateral legs since surgeries with Dr. Durrani. My whole back, neck and leg hurt so bad I could throw up." - Tonia McQueary

377. "I have much more pain. Constant right-sided headache, intensity varies but always present. The back of my neck swells. My esophagus feels like it is in a different place. My throat swells." – Kelly Hennessey

378. As stated, there are just a few examples of clients that have been discovered to have had non-FDA approved PureGen implanted into their bodies without their informed consent, in violation of both Federal and State Law, all with the knowledge of Defendants.

379. Dr. Durrani oftentimes used Puregen when performing surgeries.

380. Puregen is a product produced by Alphatec Spine.

381. Dr. Durrani was and is a paid consultant for Alphatec Spine.

382. Dr. Durrani has an ownership stake in the Alphatec Spine.

383. Puregen has never been approved by the FDA for any human use.

384. Puregen is now removed from the market for any use.

385. Dr. Durrani used the product Puregen as bone graft substitute similar to Infuse/BMP-2 during spinal surgeries.

386. Dr. Durrani, CAST staff and employees, Riverview Health Institute personnel, and Journey Lite personnel did not disclose their intent to use Puregen, nor did they inform Plaintiff that it was a product that was not approved by the FDA for human use.

387. Dr. Durrani used Puregen in Plaintiff in manners not approved by the FDA.

388. Plaintiff were not informed by Dr. Durrani, CAST staff and employees, Riverview Health Institute personnel, or any Journey Lite personnel that Dr. Durrani used Puregen in Tracy's surgeries.

389. Plaintiff would not have allowed Puregen to be used by Dr. Durrani in Tracy's surgeries in a manner that was not approved by the FDA.

390. Plaintiff would not have consented to the use of Puregen in Tracy's body if informed of the risks by Dr. Durrani, CAST staff, and employees, Riverview Health Institute personnel, or any Journey Lite personnel.

391. The written informed consent of Dr. Durrani and CAST signed by Tracy Esselman lacked the disclosure of Puregen's use in her procedures.

392. Plaintiff never received a verbal disclosure of Puregen from Dr. Durrani, CAST staff, and employees, Riverview Health Institute personnel, or any Journey Lite personnel.

PUREGEN

393. Dr. Durrani oftentimes used Puregen when performing surgeries.

394. Puregen is a product produced by Alphatec Spine.

395. Dr. Durrani was and is a paid consultant for Alphatec Spine.

396. Dr. Durrani has an ownership stake in the Alphatec Spine.

397. Puregen has never been approved by the FDA for any human use.

398. Puregen is now removed from the market for any use.

399. Dr. Durrani used the product Puregen as bone graft substitute similar to Infuse/BMP-2 during spinal surgeries.

400. Dr. Durrani, CAST staff and employees, and Journey Lite personnel did not disclose their intent to use Puregen, nor did they inform Plaintiff that it was a product that was not approved by the FDA for human use.

401. Dr. Durrani used Puregen in Plaintiff in manners not approved by the FDA.

402. Plaintiff was not informed by Dr. Durrani, CAST staff and employees, or any Journey Lite personnel that Dr. Durrani used Puregen in her surgery.

403. Plaintiff would not have allowed Puregen to be used by Dr. Durrani in her surgery in a manner that was not approved by the FDA.

404. Plaintiff would not have consented to the use of Puregen in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any Journey Lite personnel.

405. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Puregen's use in her procedures.

406. Plaintiff never received a verbal disclosure of Puregen from Dr. Durrani, CAST staff and employees, or any Journey Lite personnel.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

407. Defendant Dr. Durrani owed his patient, Plaintiff, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

408. Defendant Dr. Durrani breached his duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiff, including but not limited to improper selection for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

409. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: BATTERY

410. Dr. Durrani committed battery against Plaintiff by performing a surgery that was unnecessary, contraindicated for Plaintiff's medical condition, and for which he did not properly obtain informed consent, inter alia, by using BMP-2, PureGen and/or Baxano in

ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiff.

411. Plaintiff would not have agreed to the surgery if they knew the surgery was unnecessary, not approved by the FDA, and not indicated.

412. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: LACK OF INFORMED CONSENT

413. The informed consent forms from Dr. Durrani and CAST, which they required Plaintiff to sign, failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani and CAST each required an informed consent release.

414. In addition, no one verbally informed Plaintiff of the information and risks required for informed consent at the time of or before Plaintiff's surgery.

415. Dr. Durrani failed to inform Plaintiff of material risks and dangers inherent or potentially involved with her surgery and procedures.

416. Had Plaintiff been appropriately informed of the need or lack of need for surgery and other procedures and the risks of the procedures, Plaintiff would not have undergone the surgery or procedures.

417. As a direct and proximate result of the lack of informed consent, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

418. Dr. Durrani's conduct as described above was intentional and reckless.

419. It is outrageous and offends against the generally accepted standards of morality.

420. It was the proximate and actual cause of Plaintiff's psychological injuries, emotional injuries, mental anguish, suffering, and distress.

421. Plaintiff suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

422. Dr. Durrani made material, false representations to Plaintiff and their insurance company related to Plaintiff's treatment including: stating the surgery was necessary, that Dr. Durrani "could fix" Plaintiff, that more conservative treatment was unnecessary and futile, that the surgery would be simple or was "no big deal", that Plaintiff would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the surgery was successful, and that Plaintiff was medically stable and ready to be discharged.

423. Dr. Durrani also concealed the potential use of Infuse/BMP-2 and/or Puregen in Plaintiff's surgery, as well as other information, when he had a duty to disclose to Plaintiff his planned use of the same.

424. These misrepresentations and/or concealments were material to Plaintiff because they directly induced Plaintiff to undergo her surgery.

425. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

426. Dr. Durrani made the misrepresentations before, during and after the surgery with the intent of misleading Plaintiff and their insurance company into relying upon them.

Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgery, and to induce Plaintiff to undergo the surgery without regard to medical necessity and only for the purpose of receiving payment.

427. The misrepresentations and/or concealments were made during Plaintiff's office visits at Dr. Durrani's CAST offices.

428. Plaintiff was justified in their reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

429. As a direct and proximate result of the aforementioned fraud, Plaintiff did undergo surgery which was paid for in whole or in part by their insurance company, and suffered all damages as requested in the Prayer for Relief.

COUNT VI: SPOLIATION OF EVIDENCE

430. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

431. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

432. Dr. Durrani's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT VII: LOSS OF CONSORTIUM

433. At all times relevant, the Plaintiffs were married.

434. As a result of the wrongful acts and omissions of Dr. Durrani, Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of

society, loss of affection, loss of assistance, and loss of conjugal fellowship, all to the detriment of Plaintiffs' marital relationship.

435. All the aforesaid injuries and damages were caused proximately by the acts and omissions of Dr. Durrani.

CAST COUNTS:

COUNT I: VICARIOUS LIABILITY

436. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of CAST.

437. Dr. Durrani is in fact, the owner of CAST.

438. Defendant Dr. Durrani was performing within the scope of his employment with CAST during the care and treatment of Plaintiff.

439. Defendant CAST is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.

440. Defendant CAST is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

441. As a direct and proximate result of Defendant CAST's acts and omissions, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT II: NEGLIGENT HIRING, RETENTION, AND SUPERVISION

442. CAST provided Dr. Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.

443. CAST and Dr. Durrani participated in experiments using BMP-2 and/or Puregen bone graft on patients, including Plaintiff, without obtaining proper informed consent thereby causing harm to Plaintiff.

444. CAST breached its duty to Plaintiff, inter alia, by not supervising or controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiff at CAST.

445. The Safe Medical Device Act required entities such as CAST to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

446. Such disregard for and violations of federal law represents strong evidence that CAST negligently hired, retained, and supervised Dr. Durrani.

447. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Dr. Durrani, Plaintiff sustained all damages requested in the Prayer for Relief.

COUNT III: SPOLIATION OF EVIDENCE

448. CAST, through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, emails, billing records, paperwork and related evidence.

449. CAST, through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

450. CAST's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT III: FRAUD

451. CAST sent out billing to Plaintiff at her home following her surgeries at Journey Lite Hospital.

452. The exact dates these medical bills were sent out are reflected in those medical bills.

453. These bills constituted affirmative representations by CAST that the charges related to Plaintiff's surgeries were medically appropriate and properly documented.

454. The bills were sent with the knowledge of CAST that in fact Plaintiff's surgeries were not appropriately billed and documented and that the services rendered at Journey Lite Hospital associated with Dr. Durrani were not appropriate.

455. The bills sent by CAST to Plaintiff falsely represented that Plaintiff's surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

456. Plaintiff relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiff for CAST's services in association with Dr. Durrani's surgery.

457. As a direct and proximate result of this reliance on the billing of CAST, Plaintiff incurred medical bills that she otherwise would not have incurred.

458. CAST also either concealed from Plaintiff that they knew about Dr. Durrani, including that Infuse/BMP-2 and/or Puregen would be used in Plaintiff's surgeries, or misrepresented to Plaintiff the nature of the surgeries, and the particular risks that were involved therein.

459. CAST's concealments and misrepresentations regarding Infuse/BMP-2 and/or Puregen and the nature and risks of Plaintiff's surgeries were material facts.

460. Because of its superior position and professional role as a medical service provider, CAST had a duty to disclose these material facts to Plaintiff and a duty to refrain from misrepresenting such material facts to Plaintiff.

461. CAST intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgeries, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at Journey Lite Hospital.

462. Plaintiff was unaware that BMP-2 and/or Puregen would be used in Plaintiff's surgeries and therefore, was unaware of the health risks of Infuse/BMP-2 and/or Puregen's use in Plaintiff's spine.

463. Had Plaintiff known before Plaintiff's surgeries that Infuse/BMP-2 and/or Puregen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing therefrom, Plaintiff would not have undergone the surgery with Dr. Durrani at Journey Lite Hospital.

464. As a direct and proximate result of the fraud against plaintiff by CAST, Plaintiff sustained all damages requested in the prayer for relief.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

465. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

466. CAST's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

467. CAST omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

468. CAST's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

469. CAST was fully aware of its actions.

470. CAST was fully aware that Plaintiffs were induced by and relied upon CAST's representations at the time CAST was engaged by Plaintiffs.

471. Had Plaintiffs been aware that CAST's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

472. CAST, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

473. CAST's actions were not the result of any bona fide errors.

474. As a result of CAST's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

i. An order requiring that CAST restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

COUNT V: LOSS OF CONSORTIUM

475. At all times relevant, the Plaintiffs were married.

476. As a result of the wrongful acts and omissions of CAST, Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, loss of affection, loss of assistance, and loss of conjugal fellowship, all to the detriment of Plaintiffs' marital relationship.

477. All the aforesaid injuries and damages were caused proximately by the acts and omissions of CAST.

JOURNEY LITE OF CINCINNATI, LLC COUNTS:

COUNT I: VICARIOUS LIABILITY

478. At all times relevant, Defendant Dr. Durrani was an agent, apparent agent, and/or employee of Journey Lite.

479. Dr. Durrani is in fact, a partial owner or shareholder of Journey Lite.

480. Defendant Dr. Durrani was performing within the scope of his agency, real or apparent with Journey Lite during the care and treatment of Plaintiff.

481. Defendant Journey Lite is responsible for harm caused by acts of its agents and apparent agents for conduct that was within the scope of agency under the theory of respondeat superior.

482. Defendant Journey Lite is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

483. As a direct and proximate result of Defendant Journey Lite's acts and omissions, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, and loss of ability to perform usual and customary activities and incurred substantial medical expenses and treatment.

COUNT II: NEGLIGENT CREDENTIALING & RETENTION

484. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiff constitute physician negligence and medical malpractice.

485. Journey Lite negligently credentialed and retained Dr. Durrani as a credentialed physician by:

a. Allowing Dr. Durrani to repeatedly violate the Journey Lite bylaws with it's full knowledge of the same;

b. Failing to adequately review, look into, and otherwise investigate Dr. Durrani's educational background, work history and peer reviews when he applied for privileges at Journey Lite;

c. Ignoring complaints about Dr. Durrani's treatment of patients reported to it by Journey Lite staff, Dr. Durrani's patients and by others;

d. Ignoring Dr. Durrani's previous privilege terminations from other Cincinnati area hospitals, including Journey Lite, Deaconess Hospital, Good Samaritan Hospital, Christ Hospital and West Chester Hospital.

486. The Safe Medical Device Act required entities such as Journey Lite to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA

and the manufacturer; this was never done.

487. Such disregard for and violations of federal law represents strong evidence that Journey Lite negligently granted and retained privileges for Dr. Durrani.

488. As a direct and proximate result of the negligent credentialing and retention of Dr. Durrani, Plaintiff sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, and loss of ability to perform usual and customary activities and incurred substantial medical expenses and treatment that Plaintiff would not otherwise have incurred had Dr. Durrani not been credentialed by Journey Lite.

COUNT III: FRAUD

489. Ohio Administrative Code 3701-83-07(A)(5) states, "Each patient shall receive, if requested, a detailed explanation of facility charges including an itemized bill for services rendered.

490. The bills sent to Plaintiff, after multiple requests, were in violation Ohio Administrative Code 3701-83-07(A)(5).

491. Upon information and belief, Plaintiff believes that Dr. Durrani implanted BMP-2/or Puregen into Plaintiff. (see exhibit A)

492. Even after Plaintiff's Counsel and the Ohio Attorney General requested itemized billing, Journey Lite still did not provide an itemized breakdown of the charges; instead Journey Lite continued to provide "Account Ledgers," which contained barebones "Insurance Billing" and "Insurance Payments."

493. Due to Journey Lite's downright refusal to comply with Plaintiff's request for itemized billing, Plaintiff has been forced to file a class action suit against Journey Lite's for their egregious billing practices.

494. The bills sent by Journey Lite to Plaintiff falsely represented that Plaintiff's surgeries were appropriately indicated, performed, and medically necessary in contra-indication of the standard of care.

495. Upon information and belief, Plaintiff believes the bills requested by Plaintiff will indicate that Journey Lite Hospital falsely represented that Plaintiff's surgery was appropriately indicated, performed, and medically necessary in contra-indication of the standard of care.

496. The bills were sent to Plaintiff's insurance company with the knowledge of Journey Lite that in fact Plaintiff's surgeries were not appropriately billed and documented and that the services rendered at Journey Lite associated with Dr. Durrani were not appropriate.

497. Plaintiffs relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiffs for Journey Lite's services in association with Dr. Durrani's surgeries.

498. As a direct and proximate result of this reliance on the billing of Journey Lite, Plaintiff incurred medical bills that she otherwise would not have incurred.

499. Journey Lite also either concealed from Plaintiff that they knew about Dr. Durrani, including that Infuse/BMP-2 and/or Puregen would be used in Plaintiff's

surgeries, or misrepresented to Plaintiff the nature of the surgeries and the particular risks that were involved therein.

500. Journey Lite's concealments and misrepresentations regarding Infuse/BMP-2 and/or Puregen and the nature and risks of Plaintiff's surgeries were material facts.

501. The use of BMP-2 increases a person's chance of cancer by 3.5%.

502. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

503. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result Plaintiff has an increased fear of cancer.

504. Because of its superior position and professional role as a medical service provider, Journey Lite had a duty to disclose these material facts to Plaintiffs and a duty to refrain from misrepresenting such material facts to Plaintiffs.

505. Journey Lite intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiff in order to induce Plaintiff to undergo the surgeries, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiff at Journey Lite.

506. Plaintiff was unaware that Infuse/BMP-2 and/or Puregen would be used in Plaintiff's surgeries and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiff's spine.

507. Had Plaintiff known before Plaintiff's surgery that Puregen would be used in Plaintiff's spine and informed of the specific, harmful risks flowing there from, Plaintiff would not have undergone the surgeries with Dr. Durrani at Journey Lite.

508. Plaintiff is still awaiting billing from Journey Lite Hospital reflecting the exact totals charged for the use of BMP-2 on Plaintiff.

509. As a direct and proximate result of the fraud upon Plaintiffs by Journey Lite, Plaintiff sustained all damages requested in the prayer for relief.

COUNT IV: SPOLIATION OF EVIDENCE

510. Journey Lite through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiff's records, billing records, paperwork and related evidence.

511. Journey Lite through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiff.

512. Journey Lite's conduct was designed to disrupt Plaintiff's potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiff.

COUNT V: OHIO CONSUMER SALES PROTECTION ACT

513. Although the Ohio Consumer Sales Protection statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

514. Journey Lite's services rendered to Plaintiff constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

515. Journey Lite omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

516. Journey Lite's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and

unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

517. Journey Lite was fully aware of its actions.

518. Journey Lite was fully aware that Plaintiffs were induced by and relied upon Journey Lite's representations at the time Journey Lite was engaged by Plaintiffs.

519. Had Plaintiffs been aware that Journey Lite's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

520. Journey Lite, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

521. Journey Lite's actions were not the result of any bona fide errors.

522. As a result of Journey Lite's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

a. Loss of money paid

b. Severe aggravation and inconveniences

c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

i. An order requiring Journey Lite restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;

ii. All incidental and consequential damages incurred by Plaintiffs;

iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred;

COUNT VI: PRODUCTS LIABILITY

523. At all times Infuse/BMP-2 and Puregen are and were products as defined in R.C. § 2307.71(A)(12) and applicable law.

524. Journey Lite (aka supplier) supplied either Medtronic's (aka manufacturer) Infuse/BMP-2 or Alphatec Spine's (aka manufacturer) Puregen for surgery performed by Dr. Durrani on Plaintiff.

525. Journey Lite, as a supplier, failed to maintain either Infuse/BMP-2 or Puregen properly.

526. Journey Lite did not adequately supply all components required to use either Infuse/BMP-2 or Puregen properly.

527. Journey Lite knew or should have known the FDA requirements and Medtronic's requirements for using either Infuse/BMP-2 or Puregen.

528. Journey Lite stored either Infuse/BMP-2 or Puregen at its facility.

529. Journey Lite ordered either Infuse/BMP-2 or Puregen for surgery performed by Durrani.

530. Journey Lite did not adequately warn Plaintiff that either Infuse/BMP-2 or Puregen would be used without all FDA and manufacturer required components.

531. Journey Lite did not gain informed consent from Plaintiff for the use of either Infuse/BMP-2 or Puregen, let alone warn of the supplying of the product without FDA and manufacturer requirements.

532. Journey Lite failed to supply either Infuse/BMP-2 or Puregen (aka product) in the manner in which it was represented.

533. Journey Lite failed to provide any warning or instruction in regard to either Infuse/BMP-2 or Puregen, and failed to make sure any other party gave such warning or instruction.

534. Journey Lite intentionally billed Infuse/BMP-2 and/or Puregen as "Miscellaneous" to prevent discovery of the use of Infuse/BMP-2 and/or Puregen by Plaintiffs.

535. Plaintiff suffered physical, financial, and emotional harm due to Journey Lite's violation of the Ohio Products Liability act. Plaintiff's injuries were a foreseeable risk

536. Plaintiff did not alter, modify or change the product, nor did Plaintiff know that the product was being implanted without all required components.

537. Journey Lite knew or should have known that the product was extremely dangerous and should have exercised care to provide a warning that the product was being used and that the product was being used outside FDA and manufacturer requirements. The harm caused to Plaintiff by not providing an adequate warning was foreseeable,

538. Journey Lite knew that the product did not conform to the representation of the intended use by the manufacturer yet permitted the product to be implanted into Plaintiff.

539. Journey Lite, as a supplier, acted in an unconscionable manner in failing to supply the product without all FDA and manufacturer required components.

540. Journey Lite, as a supplier, acted in an unconscionable manner in failing to warn Plaintiff that the product was being supplied without all FDA and manufacturer required components.

541. Journey Lite's actions demonstrate they took advantage of the Plaintiffs inability, due to ignorance of the product, to understand the product being implanted without FDA and manufacturer required components.

542. Journey Lite substantially benefited financially by the use of the product as the product allowed for Journey Lite to charge more for the surgery.

543. Plaintiff suffered economic loss as defined in R.C. § 2303.71(A)(2) and applicable law.

544. Plaintiff suffered mental and physical harm due to Journey Lite's acts and omissions.

545. Plaintiff suffered emotional distress due to acts and omissions of Journey Lite and is entitled to recovery as defined in R.C. § 2307.71(A)(7) and applicable law.

546. Journey Lite violated the Ohio Products Liability Act R.C. § 2307.71-2307.80

547. Journey Lite violated R.C. § 2307.71(A)(6)

548. Journey Lite violated The Ohio Consumer Sales Practices Act R.C. § 1345.02-.03.

549. Journey Lite provided inadequate warnings are defined in R.C, § 2307.76(A) and applicable law.

COUNT VII: LOSS OF CONSORTIUM

550. At all times relevant, the Plaintiffs were married.

551. As a result of the wrongful acts and omissions of Journey Lite, Plaintiffs were caused to suffer, and will continue to suffer in the future, loss of consortium, loss of society, loss of affection, loss of assistance, and loss of conjugal fellowship, all to the detriment of Plaintiffs' marital relationship.

552. All the aforesaid injuries and damages were caused proximately by the acts and omissions of Journey Lite.

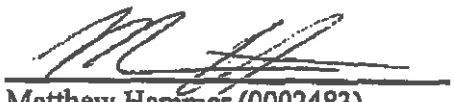
PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests and seeks justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. Past medical bills;
2. Future medical bills;
3. Lost income and benefits;
4. Lost future income and benefits;
5. Loss of ability to earn income;
6. Past pain and suffering;
7. Future pain and suffering;
8. Plaintiff seeks a finding that their injuries are catastrophic under Ohio Rev. Code §2315.18;
9. Plaintiff seeks all relief available under the Ohio Products Liability Act R.C. § 2307.71-2307.80 and applicable law;
10. All incidental costs and expenses incurred as a result of their injuries;
11. The damages to their credit as a result of their injuries;
12. Loss of consortium;
13. Punitive damages;
14. Costs;
15. Attorneys' fees;
16. Interest;
17. All property loss;
18. All other relief to which they are entitled including O.R.C. 1345.01

Based upon 1-18 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiff seeks in excess of $25,000.

Respectfully Submitted,



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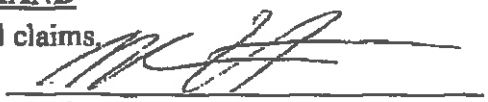
JURY DEMAND

Plaintiffs make a demand for a jury under all claims.



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